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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,704	06/01/2001	Randy L. Morningstar	687-442	2503

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EXAMINER	
FERKO, KATHRYN P	
ART UNIT	PAPER NUMBER
3743	12

DATE MAILED: 04/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,704	MORNINGSTAR, RANDY L.	
	Examiner	Art Unit	
	Kathryn Ferko	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) *20-51 and 62-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 52-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated March 4, 2003. Claims 1-19 and 52-61 are pending. The amendments to the title, specification, and drawings have been acknowledged and accepted.

Response to Arguments

1. Applicant's arguments, see Paper No. 11, filed March 4, 2003, with respect to the rejection(s)of claim(s) 1-19 and 52-61 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Pevsner in US Re. 32,348.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 5-7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Pevsner in US Re. 32,348.

Pevsner discloses an implantable balloon having a valve portion (40) having a valve body defining an inlet; a valve stem extending from the body opposite the inlet (obvious of any valve – the portion of the valve past the inlet); a piercing extending from the inlet, through the body and the stem, the valve

portion constructed from a soft, elastomeric material having memory thereby causing the piercing to remain closed and fluid-tight unless penetrated by a relatively rigid member, as recited in column 4, lines 1-30 and seen in figure 5; a balloon portion (such as 26a), integral with the valve portion, constructed and arranged to receive and hold fluids exiting the piercing opposite the inlet, as recited in column 3, lines 64-68, column 4, lines 1-30 and seen in figures 5-12; a valve stem that has at least one side (obvious of any valve), as seen in figure 5; a valve portion that is *substantially* cylindrical, as seen in figure 5; a valve body, valve stem, and inlet that are *substantially* cylindrical and *substantially* concentric, as seen in figure 5; a valve stem that has at least one side and the piercing extends through the side of the stem, as recited in column 4, lines 1-30; and a soft, elastomeric material that is silicone, as recited in column 3, line 35.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3, 4, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pevsner in US Re. 32, 348 in view of Dormandy, Jr. et al. in US Patent No. 4,819,637.

Pevsner discloses the invention as applied to claims 1, 2, 5-7 and 10. However, Pevsner does not explicitly recite a valve stem having a rounded tip; a

valve portion further having a sidewall, *laterally displaced* from the valve stem side, and integral with an inside surface of the balloon portion; a valve portion that further has a sidewall extending from the valve body, *laterally displaced* from the valve stem side; or a valve body that forms a curved web, integrally connecting the valve portion sidewall with the valve stem side, the curved web being concave and opening toward the balloon portion.

On the other hand, Dormandy, Jr. et al. teach a valve stem having a side and the valve portion further having a sidewall, *laterally displaced* from the valve stem side, and integral with an inside surface of the balloon portion and *laterally displaced* from the stem side; and a valve body that forms a curved web, integrally connecting the valve portion sidewall with the valve stem side, the curved web being concave and opening toward the balloon portion, as seen in figure 7. Therefore, it would be obvious to one with ordinary skill in the art to incorporate the teachings of Dormandy, Jr. et al. in the system of Pevsner to have *valve portion* further having a sidewall, *laterally displaced* from the valve stem side, and integral with an inside surface of the balloon portion; and a valve body that forms a curved web, integrally connecting the valve portion sidewall with the valve stem side, the curved web being concave and opening toward the balloon portion for the purpose of providing a better seal and relieve stress from the union of the balloon wall and the valve body. Furthermore, a valve stem having a rounded tip is within the scope of the invention and would be obvious to one with ordinary skill in the art.

6. Claims 11-13 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pevsner in US Re. 32,348 in view of Dormandy, Jr. et al. in US Patent No. 4,819,637.

Pevsner discloses a self-sealing medical balloon of unitary construction, implantable in a human body, having a cylindrical valve body (40) having a predetermined diameter and an upper side and a lower side; an inlet defined by the valve body lower side; a cylindrical valve stem extending upwardly from the valve body, a balloon wall (part of 26a) adapted to receive and hold fluid (note: which could mean either permanently or temporarily) extending upwardly from the valve body, the balloon wall extending upwardly from the valve body, the balloon wall having an inner diameter, while in a deflated state, which is larger than the valve stem diameter such that an annular space exists between the balloon wall and the valve stem while the balloon is deflated, the annular space is provided to relieve stress from a union of the balloon wall and the valve body when the balloon is inflated (where the annular space can be considered the interior of the balloon to the right of element 40 – the whole interior of the balloon is an annular space), as seen in figure 5; a piercing extending from the inlet, through the valve body and through the valve stem, into an inner chamber defined by the balloon, the piercing constructed and arranged to remain closed unless a substantially rigid member is pushed through the piercing, such as to inflate the balloon, whereby the piercing recloses after the member is withdrawn, thereby preventing a fluid from escaping from the inner chamber, as recited in

column 4, lines 1-30; an inlet, valve body, and valve stem that are substantially concentric, sharing a common longitudinal axis, as seen in figure 5; a piercing that follows the longitudinal axis, as recited in column 4, lines 1-30 and seen in figure 5; and a balloon that is constructed entirely of silicone, as recited in column 3, line 35.

However, Pevsner does not explicitly recite a valve stem that has a smaller diameter than the valve body diameter; a removable skirt extending downwardly from the valve body, the skirt providing a surface which may be handled during a balloon manufacturing operation without damaging the balloon wall or valve body; or a removable skirt that has an outside diameter smaller than an outside diameter of the valve body such that a ridge is formed between the valve body and the skirt.

On the other hand, Dormandy, Jr. et al. teach a valve stem that has a smaller diameter than the valve body diameter, as seen in figure 7. Therefore, it would be obvious to one with ordinary skill in the art to provide the valve of Pevsner with a valve stem that is smaller in diameter than the valve body diameter for the purpose of a better seal and relief of stresses. Furthermore, a removable skirt extending downwardly from the valve body, the skirt providing a surface which may be handled during a balloon manufacturing operation without damaging the balloon wall, or the valve body; and a removable skirt that has an outside diameter smaller than an outside diameter of the valve body such that a ridge is formed between the valve body and the skirt are known manufacturing

techniques that would be obvious to one with ordinary skill in the art, and thus, fall within the scope of the invention.

7. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pevsner in US Re. 32,348 in view of Dormandy, Jr. et al. in US Patent No. 4,819,637 as applied to claim 11 above, and further in view of Copenhaver et al. in US Patent No. 5,720,734.

Pevsner as modified by Dormandy, Jr. et al. demonstrate the invention with the exception of a piercing having a curved portion; a piercing having a straight portion and a curved portion, where the straight portion extends upwardly from the inlet and substantially parallel to the axis, the curved portion extends from the straight portion to a side of the valve stem; and an annular space that is defined on a lower side by a curved web which is concave and opening upwardly.

On the other hand, Copenhaver et al. teach a piercing having a curved portion, as seen in figure 2 and a piercing having a straight portion and a curved portion, where the straight portion extends upwardly from the inlet and substantially parallel to the axis, the curved portion extends from the straight portion to a side of the valve stem, as seen in figure 2. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Pevsner as modified by Dormandy, Jr. et al. to incorporate a piercing having a curved portion; and a piercing having a straight portion and a curved portion, where the straight portion extends upwardly from the inlet and substantially parallel to the

axis, the curved portion extends from the straight portion to a side of the valve stem for purpose of enhanced sealing properties where the piercing better closes to prevent backflow.

8. Claims 52-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pevsner in US Re. 32,348 in view of Dormandy, Jr. et al. in US Patent No. 4,819,637 and further in view of Copenhaver et al. in US Patent No. 5,720,734.

Pevsner discloses a valve (40) of unitary construction, useable to prevent fluid from escaping from an implantable balloon operably attached to the valve, the valve having a substantially cylindrical body defining an inlet, concentric with the body, opening in a direction opposite the balloon; a valve stem, integral with the body having a substantially cylindrical side, the body leading to an interior of the balloon; a piercing, defined by the valve body and the valve stem, extending from the inlet toward the balloon and leading to the interior of the balloon; a cylindrical sidewall, integral with the body, extending in a direction toward the balloon; and a valve that is unitarily constructed from an elastomeric material, specifically silicone, as recited in column 3, line 35.

However Pevsner does not explicitly recite a valve stem having a substantially rounded tip opposite the body and leading to an interior of the balloon; a piercing having a bend that curves toward the stem side; a cylindrical sidewall *radially displaced* from the stem side, thereby creating an annular space between the stem and the sidewall, the sidewall having an external surface attachable to the balloon; a curved portion, concave so as to open toward the

balloon interior, connecting the sidewall with the stem; an end portion, integral with and extending from the sidewall, which curves inwardly to define an opening having an inner diameter which is smaller than an inner diameter of the cylindrical sidewall; a cylindrical wall having a lower sidewall and an upper sidewall and a taper connecting the lower sidewall and the upper sidewall, whereby the lower sidewall has a larger outside diameter than an outside diameter of the upper sidewall; an upper sidewall and the lower sidewall have substantially equal inner diameters; a skirt extending from the body in a direction opposite the balloon; a skirt has an outer diameter smaller than an outer diameter of the valve body, thereby providing a visual and tactile definition of an extent of the skirt, such that the skirt may be removed without removing material from the valve body; or a skirt that is sized to frictionally fit within an open end of a dipping tube.

On the other hand, Copenhaver et al. teach a piercing having a bend that curves toward the stem side, as seen in figure 2. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Pevsner to include a piercing having a bend that curves toward the stem side for the purpose of providing a better seal.

Moreover, Dormandy, Jr. et al. teach a cylindrical sidewall radially displaced from the stem side, thereby creating an annular space between the stem and the sidewall, the sidewall having an external surface attachable to the balloon, as seen in figure 7; a curved portion, concave so as to open toward the

balloon interior, connecting the sidewall with the stem, as seen in figure 7; an end portion, integral with and extending from the sidewall, which curves inwardly to define an opening having an inner diameter which is smaller than an inner diameter of the cylindrical sidewall, as seen in figure 7; a cylindrical wall having a lower sidewall and an upper sidewall and a taper connecting the lower sidewall and the upper sidewall, whereby the lower sidewall has a larger outside diameter than an outside diameter of the upper sidewall, as seen in figure 7; and an upper sidewall and the lower sidewall have substantially equal inner diameters, as seen in figure 7. Therefore, it would be obvious to further modify the invention of Pevsner as modified by Copenhaver et al. to include a cylindrical sidewall radially displaced from the stem side, thereby creating an annular space between the stem and the sidewall, the sidewall having an external surface attachable to the balloon; a curved portion, concave so as to open toward the balloon interior, connecting the sidewall with the stem; an end portion, integral with and extending from the sidewall, which curves inwardly to define an opening having an inner diameter which is smaller than an inner diameter of the cylindrical sidewall; a cylindrical wall having a lower sidewall and an upper sidewall and a taper connecting the lower sidewall and the upper sidewall, whereby the lower sidewall has a larger outside diameter than an outside diameter of the upper sidewall; and an upper sidewall and the lower sidewall have substantially equal inner diameters, for the purpose of providing a better seal, preventing backflow and relieving stresses.

Furthermore, a valve stem having a substantially rounded tip opposite the body and leading to an interior of the balloon falls within the scope of the invention and would be obvious to one with ordinary skill in the art. Also a skirt extending from the body in a direction opposite the balloon; a skirt has an outer diameter smaller than an outer diameter of the valve body, thereby providing a visual and tactile definition of an extent of the skirt, such that the skirt may be removed without removing material from the valve body; and a skirt that is sized to frictionally fit within an open end of a dipping tube would also be obvious to one with ordinary skill as obvious manufacturing techniques.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 4,479,649.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF
March 25, 2003

Henry Bennett
Supervisory Patent Examiner
Group 3700